Informed Consent for the Sequential Multiple Assignment Trial

Dear Sir/Madam,

We invite you to take part in this study. Before you decide whether to participate in, you need to know why we are doing this study and what to look for. If you are unsure about anything or want to know more about the study, please ask questions while the research assistant is discussing this informed consent with you. If you have questions now or during the study, the research assistant will answer them for you. You will have plenty of time to consider the advice and recommendations from your family and friends before you make the decision.

If you are taking part in any other studies, please inform the research assistant.

PI: Fengsu Hou.

Sponsor: Shenzhen Kangning Hospital /Shenzhen Mental Health Center

Founding: Natural Science Foundation of China

Part 1 Introduction

1. Abstract

The post-discharge suicide risk of psychiatric patients is significantly higher than it is among general population and patients with other diseases. Currently, there lacks interventions for post-discharge suicide in China. The World Health Organization recommends the low-cost brief contact interventions (BCIs) for reducing the risk in areas with limited resource of mental health service. To embed BCIs into routine work in community mental health service, it is critical to determine the best frequency to contact patients and the effects of implementation. Based on BCIs, this study aims to develop an interventional strategy against post-discharge suicide for Chinese psychiatric patients; then, based on the Implementation Outcome Framework and Sequential Multiple Assignment Randomized Trial, this study also aims to determine the best frequency of

BCIs, to evaluate the implementation process and outcomes of the strategy, and the possibility and sustainability of routine implementation. Finally, the findings will provide evidence for developing innovative management against post-discharge suicide for psychiatric patients and pioneer the application of implementation science in mental health.

2. Participants

The study will recruit patients with psychotic symptoms and patients with major depressive disorder (MDD) discharged from Shenzhen Kangning Hospital, as in representative of severe and non-severe mental disorders, separately.

3. Procedure of the study

If you agreed to participate in this study, please sign at the end of this consent form. Then the research assistant will conduct a survey to collect data as following topics:

- Sociodemographic information
- Physical and mental health
- Utilization of health services and compliance to treatment
- Social connectedness and social support
- Perceived stigma and self-efficacy
- Suicide risk

Once you have finished the survey, the research assistant will help you subscribe to the study's WeChat Mini Program or help you download and log in to the application on your smartphone. If you don't use a smartphone or prefer text messages and phone calls, please tell the research assistant.

After discharge, you will receive brief contact messages through WeChat, the application, text messages, or phone calls.

At 1-, 3-, 6- and 12-month after your discharge, there will be follow-up surveys.

4. Potential risk and coping strategy

A possible risk in this study is the leakage of personal information, including sociodemographic information, psychiatric diagnosis, and suicide risk.

This study affirms that patients' refusal to participate in the study during the informed consent process or withdrawal during the study will not affect the quality of medical services received from Shenzhen Kangning Hospital/ Shenzhen Mental Health Center, and

the study team will ensure that patients' rights will not be violated.

All data is stored in encrypted form and backed up on a storage device not connected to the Internet. Only the principal investigator and specific analysts have access to view, manage, and analyze the data.

During analysis, all processes will be only performed on the computer dedicated to this study. Copying or dissemination data in any format and method is strictly prohibited.

There will be follow-up surveys at 1, 3, 6 and 12 months after discharge. If the survey results indicate you relapsed or were at risk of suicide, we will intervene and help you as following ways:

- The research team will cooperate with the crisis intervention team from Shenzhen Kangning Hospital. We will try to contact you, initiate psychological crisis intervention, encourage you to visit out-patient clinic, and assist in treatment as needed.
- The research team will contact your family to inform them of your suicide risk, encourage them to accompany you to visit out-patient clinic, and advise on home care and precautions for managing suicide risk.
- If you relapsed, the research team will cooperate with the clinical staff of Shenzhen Kangning Hospital to contact you, explain your current symptoms, encourage you to take medicine as prescribed and to visit out-patient clinic timely.

Lastly, if you are found to be at risk of violent behaviors towards the public, the research team will collaborate with the Shenzhen Kangning Hospital to contact your family members to inform them of the risk, notify the community mental health workers in your community to conduct face-to-face visits, and assist in treatment as needed, in accordance with the requirements of the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 version).

5. Benefits

Participation in this study does not affect the quality of clinical care you receive. However, through this study, you can understand your current mental health status and receive reminders for follow-up visits, which beneficial for early prevention, diagnosis, and intervention.

6. Cost

You don't need to pay any fees to join the study.

7. Compensation

By taking part in this study, we will pay you RMB 100 Yuan as compensation for the cost of your time.

8. Participation principle

Your participation in this study is voluntary. You may opt out at any time during the study. There will be no prejudice and your benefits will not be compromised.

Refusal or withdrawal from the survey will not affect your future access to clinical care or the quality of the services involved.

9. Privacy

Your personal information is confidential and will be unidentified, encrypted, and stored. All data collected in this study are only for the research purposes and there is no commercial or other use. The results of this study may be published in academic journals/books, but your name or any other information that identifies you will not appear in any published materials. Subject-identifiable information will not be disclosed to members outside the research team unless your permission is obtained. Only the principal investigator and specific analysts have access to view, manage, and analyze the data. To ensure that the research is conducted in accordance with the regulations, members of the government administration or ethics review committee will have access to your personal information as required.

10. Contact information

If you have any questions related to this study, please contact the principal investigator: Fengsu Hou，18502864780.

If there are any questions about your rights/interests, or if you want to report the difficulties, dissatisfaction or concerns encountered about participating in this study, or if you want to provide comments and suggestions related to this study, please contact the Ethics Committee Office of Shenzhen Kangning Hospital. Telephone number 0755-

82926524. Email: kangning_ethics@163.com.

Part 2 Informed Consent and Signature

Consent declaration:

I have fully discussed and understood the background, purposes, and procedures of this study. I have been given plenty of time and opportunity to ask questions, and the answers to my questions are satisfactory. I was also told who to contact when I had questions or wanted further information. I have read this informed consent form and I agree to participate in this study. I understand that I can withdraw from this study at any point without any reason.

I agree to participate in this study and I will complete the study with the assistance of research assistants.

Signature：

Date：

Informed Consent for Qualitative Interviews

Dear Sir/Madam,

We invite you to take part in this study. Before you decide whether to participate in, you need to know why we are doing this study and what to look for. If you are unsure about anything or want to know more about the study, please ask questions while the research assistant is discussing this informed consent with you. If you have questions now or during the study, the research assistant will answer them for you. You will have plenty of time to consider the advice and recommendations from your family and friends before you make the decision.

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1. Abstract

The post-discharge suicide risk of psychiatric patients is significantly higher than it among general population and patients with other diseases. Currently, there lacks interventions for post-discharge suicide in China. The World Health Organization recommends the low-cost brief contact interventions (BCIs) for reducing the risk in areas with limited resource of mental health service. To embed BCIs into routine work in community mental health service, it is critical to determine the best frequency to contact patients and the effects of implementation. Based on BCIs, this study aims to develop an interventional strategy against post-discharge suicide for Chinese psychiatric patients; then, based on the Implementation Outcome Framework and Sequential Multiple Assignment Randomized Trial, this study also aims to determine the best frequency of BCIs, to evaluate the implementation process and outcomes of the strategy, and the

possibility and sustainability of routine implementation. Finally, the findings will provide evidence for developing innovative management against post-discharge suicide for psychiatric patients and pioneer the application of implementation science in mental health.

2. Participants

The study will recruit patients with psychotic symptoms and patients with major depressive disorder (MDD) discharged from Shenzhen Kangning Hospital, their lay health supporters, psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers.

3. Procedure of the study

If you agreed to participate in this study, please sign at the end of this consent form. Then the research assistant will conduct a survey about your sociodemographic information and then conduct the interview to explore your opinions about following topics:

For patients and lay health providers

- Previous experience of discharge from psychiatric facilities
- Expectations and needs for post-discharge suicide risk management
- Social connectedness and social support
- Attitudes towards brief contact intervention
- Evaluations related to the implementation of brief contact intervention

For psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers

- Experience related to suicide risk management
- Suggestions and expectations for suicide risk management of patients with mental disorder
- Patients' social connectedness and social support
- Attitudes towards brief contact intervention
- Evaluations related to the implementation of brief contact intervention

Interviews will be recorded for analysis.

4. Potential risk and coping strategy

A possible risk in this study is the leakage of personal information, including

sociodemographic information, psychiatric diagnosis, and suicide risk.

This study affirms that patients' refusal to participate in the study during the informed consent process or withdrawal during the study will not affect the quality of medical services received from Shenzhen Kangning Hospital/ Shenzhen Mental Health Center, and the study team will ensure that patients' rights will not be violated.

All data is stored in encrypted form and backed up on a storage device not connected to the Internet. Only the principal investigator and specific analysts have access to view, manage, and analyze the data.

During analysis, all processes will be only performed on the computer dedicated to this study. Copying or dissemination data in any format and method is strictly prohibited.

5. Benefits

Participation in this study does not affect the quality of clinical care you receive. However, through this study, you can understand your current mental health status and receive reminders for follow-up visits, which are beneficial for early prevention, diagnosis, and intervention.

6. Cost

You don’t need to pay any fees to join the study.

7. Compensation

By taking part in this study, we will pay you RMB 100 Yuan as compensation for the cost of your time.

8. Participation principle

Your participation in this study is voluntary. You may opt out at any time during the study. There will be no prejudice and your benefits will not be compromised.

Refusal or withdrawal from the interview will not affect your future access to clinical care or the quality of the services involved.

9. Privacy

Your personal information is confidential and will be unidentified, encrypted, and stored. All data collected in this study are only for the research purposes and there is no

commercial or other use. The results of this study may be published in academic journals/books, but your name or any other information that identifies you will not appear in any published materials. Subject-identifiable information will not be disclosed to members outside the research team unless your permission is obtained. Only the principal investigator and specific analysts have access to view, manage, and analyze the data. To ensure that the research is conducted in accordance with the regulations, members of the government administration or ethics review committee will have access to your personal information as required.

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